An Evaluation of Palliative Care in Rural Tanzania where Availability of Oral Morphine is Intermittent or Absent

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Candidate: Kristopher Hartwig MD

Supervisor: Elma de Vries

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Abstract

Introduction. In Tanzania, palliative care is relatively new, and faces the common challenges of access to services, crucial medications, and education. Since 2004, an initiative within the health system of the Evangelical Lutheran Church in Tanzania (ELCT) began to promote and develop palliative care, using as a model the Selian Hospice and Palliative Care Programme. The hospitals which are the sites for team development and service delivery are widely scattered throughout rural Tanzania. Access to oral morphine was only a dream, as it is for much of the rural population of the world. In 2007, a program called CHAT (**C**ontinuum of care for people living with **H**IV/**A**IDS in **T**anzania), funded by the U.S. government, allowed the up-scaling of these palliative care programs, resulting in 13 strong and mature teams by 2011, though still lacking oral morphine. Part of the monitoring and quality assurance of the program has been use of a tool developed by APCA: the APCA African Palliative Outcome Scale (POS). Hundreds of people living with cancer and HIV were subjected to the questions of the tool, which was always sent on to the core supervising team for assessment and feedback. Tramadol was the strongest analgesic available to the teams throughout the study time.

Methodology: 145 APCA African POS results on cancer patients were assessed, looking at differences in pain scores (0 to 5 scale) over time as well as assessing the other domains of care (psychological, spiritual, social, and family). 11 Palliative care nurses were also interviewed, asked to reflect on specific cases from their experience with both good and bad pain control. 5 of the nurses came from Selian, with access to oral morphine, while 6 of them came from the CHAT hospitals.

Results: Significant improvement in pain scores over 4 weeks was noted (3.83 to 2.31, $p < 0.0001$). All other domains assessed in the POS also improved significantly. Nurse interviews revealed an emphasis on the holistic approach and a strong preference for having access to oral morphine.

Conclusion: In this rural Tanzanian environment, effective palliative care services – including pain control - were delivered even in the absence of oral morphine. Such services can become a strong advocacy at the government level for achieving breakthroughs in palliative care, including access to oral morphine.

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1. Introduction/Background

1.1 Palliative Care

Palliative care is a critical component of the medical approach to life-threatening diseases, particularly with incurable conditions such as terminal cancer. In rural Tanzania, as in much of the world, diagnosis of cancer occurs late in the clinical course of disease, with the result that palliative care is often the best and only option for care[1,2]. The World Health Organization (WHO) defines palliative care as a holistic approach for patients and their families who are living with life-threatening diseases. One emphasis is on the ability to treat pain holistically, including the provision of medication to alleviate that pain[3]. Yet few palliative care services are available, most particularly in rural parts of the world, due to a lack of trained professionals, a lack of medication (opioids especially), and a lack of integration into standard medical care[4]. A recent analysis out of the International Observatory on End of Life Care shows that just over 50% of the world's countries have any form of palliative care, and of those a further 30% have only "isolated services"[5].

1.2 Relief from Pain

Oral morphine is widely accepted as the first-line drug for treatment of cancer pain[6]. But while ongoing advocacy is working towards recognition of pain relief as a basic human right[4,7], it is of limited availability in much of the world. The result being that people living with cancer are often left to die at home, or in the hospital, with no effective way to relieve their physical suffering. Most of the world's population has access to little or no opioid drugs for pain treatment[8].

1.3 Study Setting/Tanzania

Tanzania is a country of over 40 million people, and it is estimated that over 50,000 people per year will die of cancer[9]. Due primarily to vast distances to travel and the immobility of the very sick, less than 10% of this population might access a palliative care service. Even when such a service is available, oral morphine may be in limited supply, and follow-up (reassessments, refills) is usually very challenging.

Palliative care is relatively new to Tanzania. Initial efforts came from the Ocean Road Cancer Institute (ORCI) in Dar es Salaam, headed by Dr. Twalib Ngoma, and this institution continues to provide leadership in this area. Training and advocacy for palliative care date from the early 90's.

However it was not until the turn of the century that other sites began concerted efforts at palliative care provision. By 2002 there were three further sites: PASADA (Dar es Salaam), Muheza (Tanga Region), and Selian (Arusha Region)[10].

Consumption of morphine remains low in Tanzania. Per capita consumption of morphine in 2005 is listed at 0.51 mg per capita[8].This compares to 6 mg per capita for South Africa and 565 mg per capita in the United States. In the case of Tanzania, if only a quarter of the people estimated to have cancer in 2010 would need oral morphine continuously for moderate to severe pain (50,000/4 = 12,500), and only 20 mg daily were required for pain control, it would take 2.28 mg per capita consumption to meet that need (based on a current population of roughly 40 million). Considering that Kenya, with more widely available oral morphine than Tanzania, used a per capita consumption of about 1 mg per capita, it is unlikely that Tanzania is approaching anything near the necessary consumption to achieve pain control for a significant portion of their population living with cancer.

1.4 Selian and ELCT

In 2004, the Evangelical Lutheran Church in Tanzania (ELCT) began a program in palliative care, emulating the growth of Selian's service. Using a hospital-based approach, trained palliative care teams were developed through 18 rural ELCT hospitals, widely scattered throughout the country (see Map in Appendix I). In 2007 the ELCT program, in collaboration with the Foundation for Hospices in Sub-Saharan Africa (FHSSA) and the African Palliative Care Association (APCA), received funding from the President's Emergency Program for AIDS Relief (PEPFAR, out of the United States) to initiate the program now known as CHAT (**C**ontinuum of Care for people living with **H**IV/**A**IDS in **T**anzania)[11-14]. Tanzania is one of the target countries for PEPFAR. Its approach, as organized by the National AIDS Control Program (NACP), is to provide home-based care (HBC) to all people living with HIV, with the spectrum of HIV services available either at the nearby health facility or the home. Trained community volunteers (a 21 day curriculum organized by the NACP), health professional supervisors, counselling and testing, anti-retroviral drug access, and palliative care are all part of this spectrum. The CHAT program is unique in several aspects: starting with pre-existing palliative care services; having a supervising multi-disciplinary team; having a mobile team with vehicle transport; being inclusive of non-HIV cases, cancer in particular; and monitoring quality of care routinely with a quality of life (QoL) assessment tool. Thus CHAT is a

HBC service based at the hospital, a multi-disciplinary team of professionals providing oversight and backup care to a larger team of lay volunteers from the community. Care is provided in homes, on hospital wards, at hospital-based outpatient clinics, and through mobile clinics.

1.5 Rural areas and access to oral morphine

As mentioned above, oral morphine is not accessible in most of rural Tanzania, including these 13 sites (13 of the 18 ELCT hospitals are part of CHAT). Thus the practice of pain management has been in the context of significant limitations. As a result each team of health professionals has become proficient in the systematic use of other analgesics, namely, tramadol, ibuprofen, and paracetamol as analgesics for somatic pain, and amitriptyline and carbamazapine for treatment of neuropathic pain. These medications are provided free of charge to their clients by the respective palliative care teams.

This experience of provision of palliative care raises questions. Whereas studies have shown the benefit for people living with HIV to be linked to HBC programs[15], there is little information about such care for cancer patients where oral morphine is lacking. While it might be intuitive that global well-being for any patient would be enhanced by attention from a multidisciplinary team – in the ELCT hospitals a Nurse, Nurse Assistant, Clinician, Social Worker, and Chaplain – there is still the issue of physical pain. What is the perceived efficacy of such care when morphine is not available? Is this experience able to be generalized to other settings?

Traditional palliative care development has focused on three key issues as outlined by the WHO: inclusion in national health policy, education, and availability of oral morphine[16].With the advent of wide-spread home care and anti-retroviral therapy for people living with HIV, however, the landscape of palliative care in Tanzania has changed. Fewer people with HIV are dying, with palliative care efforts in areas of high HIV prevalence now finding their biggest challenges in psychosocial and reproductive issues: stigma, disclosure, and human rights in regards to autonomy in balance with social justice and public health[17]. Pain management as being integral to palliative care remains critical in the HIV context, but it is now in a different and perhaps less prominent position as opportunistic infections are less common and world-wide clinical experience steers treatment towards less toxic anti-viral regimens[18].

Widespread home care programs in Tanzania emphasize care for people living with HIV, many of whom also have cancer (Kaposi's Sarcoma, cervical cancer, lymphomas), and yet these programs lack any special focus on effective treatment of pain. Indeed, oral morphine is only reliably available in 5 sites country-wide: Ocean Road Cancer Institute, PASADA, Muheza, Selian and, since September 2009, Kilimanjaro Christian Medical Centre[10]. Practically, this means that only the Northeast and Coastal parts of the country have the possibility of ready access to this drug. Even where oral morphine is available, the combination of a limited number of prescribers (only Medical Doctors may prescribe), limited education for health professionals, and even limited stocks of the drug means that very few people in need are likely to receive it.

1.6 Study Purpose and Research Questions

The purpose of this study was to assess the quality of palliative care for cancer patients in rural Tanzania as provided by palliative care teams, 80% of whose clients are living with HIV. In this context oral morphine is not available and it might be some years before it is. Teams are nonetheless trained in the use of the WHO Analgesic Ladder, attempting to treat moderate to severe pain for HIV and cancer patients with the drugs which they have at their disposal. These drugs include tramadol, ibuprofen, diclofenac, and paracetamol.

What is the effect on palliative care services when the most important tool for treating pain – oral morphine - is not available? What insights have been gained by the nursing profession in meeting the challenges of working with such limited resources? What difference would oral morphine make if it was in fact available in such environments?

2. Literature Review

2.1 Opioid Availability

The WHO in 2002 included in its definition of palliative care "effective assessment and treatment of pain and other problems whether physical, psychological, or spiritual". Oral morphine, or its equivalent, is the gold standard for treating moderate to severe cancer pain[19-21]. Step 3 on the WHO Analgesic Ladder refers to use of strong opioids i.e. an opioid that does not have a dose ceiling, and thus can be titrated to the person's pain over time[3].

Logie found that most of the world is without access to oral morphine, and even where morphine is legally available its use is very low due to fears concerning addiction and consequent tight regulations[22]. While world-wide advocacy for accessing oral morphine is a main priority in the development of palliative care, the current picture is not encouraging[23].The implication of limited to no access to a strong opioid drug is that effective pain management is not possible in such environments. Gwyther et al, and Human Rights Watch, emphasize that in advocacy work access to palliative care as a basic human right is strongly linked to regulatory barriers to oral morphine being reduced[4,7].

The Step 2, or weak opioid class of drugs, are less restricted by the Single Convention on Narcotic Drugs[24] but are also less effective in relieving pain. Little is written about the provision of palliative care for cancer patients in the absence of Step 3 (strong opioid) drugs. A literature review failed to find any papers addressing such care. Yet anecdotal communications with colleagues in East Africa and India indicate that such situations exist, whether because of interrupted supply of oral morphine or because of being in an area which has yet to have access to oral morphine.

Widely observed but likewise little published is that the usual doses of opioid drugs in East Africa tend to be much lower than those in Europe or North America. Daily dosing of morphine in East Africa is commonly in the 20 to 30 mg range, with a "big" dose approaching 60 mg/day (personal communication with prescribers at Muheza Hospice, ORCI, PASADA, and Nairobi Hospice from 2010-2011). Yet there is little information in the literature regarding this phenomenon. A review of oral morphine use at Selian Hospice in northern Tanzania in 2008 revealed an average daily dose of oral morphine to be 27 milligrams; in 2009 it was 24 mg/d. An in-patient service in Malawi uses an average daily dose of 30 mg/d[25]. In comparison, a

paper assessing the Edmonton Staging System for cancer pain lists doses less than 60 mg/d of oral morphine as "low" and doses greater than 300 mg/d as "high"[26]. An assessment of oral morphine in chronic cancer pain from Oxford, England noted a median dose of 90 mg/d with a mean dose of 223 mg/d[27].

In Tanzania tramadol is currently the most widely available weak opioid drug. Its pain control properties have been well studied, and it is considered a WHO "Step 2" analgesic drug, having a usual dosing ceiling of 400 mg/day in adults[28]. Dose equivalency tables vary in ascribing a tramadol to morphine potency ratio from 10:1 to 20:1[29,30]. One study out of Germany compared high dose tramadol (average 428 mg/d) with low dose morphine (42 mg/d) and found comparable efficacy in terms of pain control and less side-effects in the tramadol group[31]. Thus, in theory, tramadol might be useful in the treatment of mild to moderate cancer pain in East Africa, though unable to match the potency of higher doses of morphine. Additional limitations of tramadol include limited efficacy, if any, in the treatment of dyspnoea (no references relating studies of tramadol in dyspnoea treatment). Also, being mostly available in capsule form (though intravenous also available) makes dosing versatility a problem, for example when much lower doses are needed for children, or with obstructing cancers such as that of carcinoma of the oesophagus. Therefore, while a lot of information about tramadol exists, there is no existing literature regarding its utility when there are not any more potent opioids available.

2.2 Pain Assessment in Africa

Careful pain assessment is one of the core principles of delivering effective palliative care. This has been true in African palliative care service delivery as well. The usual tools, such as numerical rating scales[32], have been used in various country settings. Additionally, there has been the development of a broader assessment tool, the APCA African Palliative Care Outcome Scale (APCA African POS), which utilizes a 0 to 5 scale and the 5 digits of the hand as the visual corollary. This broader approach to pain – psychological, social, spiritual, and family questions also come in - is in keeping with the palliative care approach towards holistic assessment. It is also aligned with the concept of "total pain", whereby as many facets of suffering in a person's life as possible are considered, with the goal of achieving pain relief, and quality of life, through a coordinated effort by the entire palliative care team.

The advent of the APCA African POS in 2007 provided the continent with a validated tool for holistic assessment that had been tested in a variety of African contexts[33,34], Harding et al point out that it also gives palliative care in the African setting a standardized tool with which to measure outcomes, including pain[35]. That pain is very prevalent in cancer patients in Africa – as elsewhere – is well known[36,37]. In a study of cancer patients in Uganda and South Africa, Harding et al offer further information, highlighting the prevalence of pain and other symptoms. They found that 87% of such people are experiencing pain[38].

Being relatively new, literature is limited on the use of the APCA African POS in terms of measured outcomes over a period of time (typically being 4 visits 1 week apart in the context of ongoing palliative care services). Loy et al used this tool, and show clearly that those outcomes for people living with HIV are better if provided in the context of a palliative care team[39]. While showing the improvement in quality of life for such patients living with HIV and receiving palliative care, there is no information regarding people living with cancer.

Another question in the area of intervention for pain relief: how much pain relief is necessary such that a patient finds it meaningful? Or, in terms of using a pain scale such as the 0 to 10 visual analogue, what degree of pain reduction is meaningful? Farrar et al noted that a 20 to 30% improvement in chronic pain patients (non-cancer) was needed in order to be associated with meaningful changes in other quality of life indicators i.e. sleep, mobility[40,41]. Traditionally, palliative care uses a change of 20% to be considered of significant impact, although extensive searching could not find an evidence base for this standard. Fainsinger et al suggest a 3/10 pain rating (or less) over 3 days as indicative of stable pain control[42].

2.3 Rationale for the Study**:** Literature is lacking about the efficacy and quality of palliative care for cancer patients in environments which lack access to potent opioid drugs such as oral morphine. Yet such patients desperately need holistic care, including attention to pain and other symptoms, even if the ideal drugs and tools are not yet available. From experience and personal communication, people clearly appreciate holistic care, particularly within their home environments, yet the question remains: what is the quality of such care when the primary medical tool (oral morphine for effective pain control) is lacking? Are there lessons to be learned from the delivery of such care? Can a significant experience in rural

Tanzania, where limited or no access to certain drugs is a fact of life, provide insights for the rest of the world?

3. Methodology

3.1 Aim: to assess the effect of limited or no access to oral morphine on the delivery of palliative care in rural Tanzania.

3.2 Objectives:

- To use a retrospective cohort analysis to assess the effectiveness, from the patient's perspective, of weak opioid analgesia in cancer pain management in rural Tanzania.
- To assess patient outcomes in quality of life areas as evaluated by the APCA African POS for people living with cancer and receiving palliative care in rural Tanzania.
- To assess the effectiveness of palliative care of cancer patients in both morphine-accessible and morphine non-accessible environments in Tanzania from the palliative care nursing perspective.
- To assess the impact on palliative care nursing staff on the provision of palliative care to cancer patients in morphine-accessible and morphine non-accessible environments in Tanzania.

There are two aspects to the research. The first aspect is a quantitative study involving a retrospective cohort analysis of cancer patients who do not have access to oral morphine. The second aspect is a qualitative analysis of interviews with 11 palliative care nurses, 6 from teams not having access to oral morphine and 5 from a team having access to oral morphine.

3.3 The Retrospective Cohort Analysis: As outlined above, as part of the CHAT project's ongoing quality assessment the APCA African POS was administered to all new patients having cancer and at one or two new HIV clients each month. CHAT began its formal training, including the APCA African POS, with 7 hospital teams in November of 2007 and 6 hospital teams in February of 2008. Subsequent site visits as well as larger all-hospital meetings emphasized review and observation of how the APCA African POS was being administered. A "learning curve" time was definitely present; by January of 2009 all teams had become well-versed in administration and reporting of this tool. Thus results from the APCA African POS, for the purposes of this study, are considered valid from January 2009 onwards.

The person performing the APCA African POS was either the Nurse

Coordinator of the team or the part-time Team Clinician. Training and ongoing follow-up was given to both cadres throughout the project and study period.

Pain management was uniformly taught and mentored to all of the teams. Tramadol was administered to all patients with severe pain, up to a maximum dose of 400 mg/d. Combining with ibuprofen, paracetamol, and/or amitriptyline was done according to patient response and tolerability. There were no shortages of any of these drugs throughout the study period.

Reports were submitted to the central ELCT office on a monthly basis. Feedback on reports was done electronically (email). All data was transcribed by the researcher from hard copy to the online database used by the CHAT project. Hard copy and online data remain available for review and analysis.

The APCA African POS is meant to be administered four times over a period of 2 to 4 weeks. It has been validated for people over the age of 18 years and with a variety of disease conditions[36]. Swahili was the working language in all instances, and the version being used was unchanged throughout the study time.

For the purposes of this study, only people living with cancer, being over 18 years of age, and having been assessed at least 3 times using the APCA African POS were included.

3.4 Study Population:

i. Selection criteria:
    1. Inclusion
        a. Over 18 years
        b. Cancer as a diagnosis (including some people with HIV)
        c. Assessed at least 3 times out of the possible 4 for APCA POS
    2. Exclusion
        a. Under 18 years of age
        b. non-cancer diagnosis
        c. Died before completion of APCA POS
        d. Assessed less than 3 times

e. Incomplete charting of the APCA POS

ii. Sampling: all CHAT program cancer patients between January 2009 and December 2010. It is generally accepted that a meaningful reduction in pain is at least 20%. Calculation of sample size is based on that number needed to show that a 20% drop in pain is statistically significant; if indeed the CHAT interventions result in a significant pain reduction. The minimal number of patients to be evaluated was calculated to be 100.

Those people who died before the requisite number of visits were completed, or who had incomplete charting of the POS, were excluded. Although many clients were assessed multiple times with the APCA African POS, only the first set of visits is included for purposes of this study.

The period of time included in the analysis is January 2009 up to December 2010.

3.5 Analysis of the Retrospective Cohort Analysis: Statistical analysis was organized so as to have all of the data compiled in Microsoft Excel format. Analysis was done using Excel software ("Analyse it"). Comparison in pain levels (on a 0 to 5 scale) are made between the first and last visit (visit 1 vs. visit 4) as ascertained on the APCA African POS Question 1.

The Shapiro-Wilk test was used to investigate whether numerical variables were normally distributed. For bivariate analysis the Wilcoxon Sum Rank test was applied to compare groups. Descriptive analysis was done based on sites, age, and gender. Key outcome variables were pain and overall quality of life measures:

i. Comparison in pain levels (on a 0 to 5 scale) were assessed between first and last visit as ascertained on the APCA POS Question number one.
ii. Comparison in quality of life change was assessed by calculating a global score (total APCA POS score organized so that for each question the "0" represents the most positive score while "5" represents the most negative score).

3.6 The Qualitative Analysis of two groups of Palliative Care Nurses: Two groups of palliative care nurses were subjected to semi-structured interviews (Appendix VII). All nurses have extensive training and experience in the field of palliative care. 5 nurses are from the Selian Hospice and Palliative Care Programme, which has had access to oral morphine since 2003. The other 6 nurses are from various CHAT hospitals, none of which had access to oral morphine during the time of the study. Each nurse was asked about specific cases regarding pain control in patients having cancer: one case where pain control was poor; another case where pain control was very good. Each interview concluded with a question about the value of delivering palliative care in the absence of oral morphine, and then an invitation to the nurse to make any general closing remarks. A further question evolved as it became clear from the Selian nurses that the only cases of poor pain control were not using oral morphine: "Do you recall any cases of patients using oral morphine where the pain was not controlled?"

The CHAT Nurses were chosen as being the most experienced out of the group of 13 Nurses. 3 hold Diplomas in Palliative Care; the other 3 have at least 7 years of experience in PC. All of the Selian cadre of Nurses were interviewed. Their experience in PC ranges from 5 to 12 years. As Pickard describes it in her book on research methods this was purposeful sampling in two regards[43]. First, the most experienced and knowledgeable of the CHAT Nurses were chosen. Secondly, of the few palliative care nurses in Tanzania, those at Selian represent a long-term experience within a system comparable to that of the CHAT Nurses.

Interviews were conducted in Swahili (9) or English (2) by the researcher, after informed consent was obtained from each of the respective nurses. Translation (Swahili to English) and transcription were likewise performed by the researcher. After audio recording of each interview, transcription was done for the 2 English interviews, while transcription and translation were simultaneous for the 9 Swahili interviews.

3.7 Analysis of the Nurse Interviews: Thematic analysis was done looking for common areas of thought shared by the nurses being interviewed, with attention to there being the two different groups, one having access to oral morphine and the other not. As suggested by Aronson, thematic analysis is one of the varieties of methodologies for evaluating information from

informants[45] Patterns of information, or themes, are identified. Within each theme there may also be sub-themes. The collection of sub-themes and themes should inform a comprehensive view of the information collected.

Medical and nursing peer review – within the ELCT health system – of the translations and transcripts was done, in order to cross-check for the validity of the comments made by nurses who had been interviewed. As the peers involved had personal knowledge of each nurse, this process was helpful in affirming the trustworthiness and objectivity of the data.

3.8 Ethical Considerations: Ethical approval for this study was granted by the University of Cape Town and also the National Institute of Medical Research of Tanzania (see Appendices).

Approval for use of data was requested from FHSSA, APCA, and each hospital site from which data was collected. Consent for the Nurse interviews was requested in each case (see Appendices for letters requesting consent).

Confidentiality was maintained with the nurse interviews by keeping recordings and transcriptions in a secure, locked place. The nurses are only identified by number, with the key to the particular names kept locked up. For the patient data, the researcher's office only has access to "patient numbers", with the key to the patient names kept at the respective sites. Thus names are not known to the researcher.

Data storage were kept in two sites: hard copies in a locked file and office; and soft copies at a password-protected website owned by FHSSA.

4. Results

4.1 Retrospective Cohort Analysis

145 APCA African POS administered to cancer patients qualified for inclusion in the study in the area of pain control (Question 1). All 13 sites contributed, although the distribution varied widely. 2 sites had only 1 fully completed and eligible APCA POS while 3 sites had more than 20. Morphine was not available at any of the sites. There were more female (87) than male (58) patients (60% to 40%). The average age was 57 years. See Table 1 for disaggregation by site and gender, with average first and last pain scores also noted for each site.

An Excel spreadsheet captured the data for all 145 patients. Table 2 shows the average APCA POS scores for each visit. Tables 3 and 4 show the averages by gender. In questions 4 through 9 the numbers are reversed (highlighted in blue). This is in order to align the numbers so that all "high" scores are "bad" and all "low" scores are good.

TABLE 1: Disaggregation by Site and Gender						
HOSPITAL	**#**	**Avg. Age**	**Male**	**Female**	**Visit 1 Avg. Pain**	**Visit 4 Avg. Pain**
Matema	26	54	15	11	4.42	2.46
Itete	13	58	7	6	3.00	1.92
Haydom	21	52	6	15	3.10	3.00
Bunda	8	43	4	4	4.75	3.38
Marangu	6	59	3	3	4.00	1.67
Bumbuli	6	58	2	4	3.33	1.67
Iambi	23	54	7	16	3.52	1.91
Ndolage	8	69	3	5	5.00	1.00
Nyakahanga	9	61	2	7	4.11	2.56
Nkoaranga	7	64	1	6	2.57	2.00
Ilembula	1	55	0	1	3.00	2.00
Gonja	1	56	1	0	3.00	3.00
Machame	16	64	7	9	4.56	2.63
	145	**57**	**40%**	**60%**	**3.83**	**2.31**

Table 2: Average Scores per Visit

		Visit 1	Visit 2	Visit 3	Visit 4
Q1. Please rate your pain (from 0 = no pain to 5 = worst/overwhelming pain) during the last 3 days	**0 (no pain) - 5 (worst/overwhelming pain)**	***3.83***	**3.08**	**2.72**	***2.31***
Q2. Have any other symptoms (e.g. nausea, coughing or constipation) been affecting how you feel in the last 3 days?	**0 (not at all) - 5 (overwhelmingly)**	**2.58**	**2.05**	**1.68**	**1.50**
Q3. Have you been feeling worried about your illness in the past 3 days?	**0 (not at all) - 5 (overwhelming worry)**	**3.39**	**2.67**	**2.31**	**2.10**
Q4. Over the past 3 days, have you been able to share how you are feeling with your family or friends?	**0 (not at all) - 5 (yes, I've talked freely)**	3.46/ **1.54**	3.84/ **1.16**	4.06/ **0.94**	4.15/ **0.85**
Q5. Over the past 3 days have you felt that life was worthwhile?	**0 (no, not at all) - 5 (Yes, all the time)**	1.95/ **3.05**	2.52/ **2.48**	2.94/ **2.06**	2.95/ **2.05**
Q6. Over the past 3 days, have you felt at peace?	**0 (no, not at all) - 5 (Yes, all the time)**	1.80/ **3.20**	2.39/ **2.61**	2.73/ **2.27**	2.84/ **2.16**
Q7 Have you had enough help and advice for your family to plan for the future?	**0 (not at all) - 5 (as much as wanted)**	2.94/ **2.06**	3.70/ **1.30**	3.99/ **1.01**	4.08/ **0.92**
Q8. How much information have you and your family been given?	**0 (none) - 5 (as much as wanted) N/A**	3.30/ **1.70**	4.01/ **0.99**	4.40/ **0.60**	4.63/ **0.37**
Q9. How confident does the family feel caring for ____?	**0 (not at all) - 5 (very confident) N/A**	4.09/ **0.91**	4.34/ **0.66**	4.45/ **0.55**	4.46/ **0.54**
Q10. Has the family been feeling worried about the patient over the last 3 days?	**0 (not at all) - 5 (severe worry) N/A**	**3.08**	**2.58**	**2.19**	**2.10**
AVERAGE "GLOBAL SCORE" on a 0 – 5 scale where 0 is good		***2.53***	***1.96***	***1.63***	***1.49***

Table 3: Average Scores Female

		Visit 1	Visit 2	Visit 3	Visit 4

Q1. Please rate your pain (from 0 = no pain to 5 = worst/overwhelming pain) during the last 3 days	**0 (no pain) - 5 (worst/overwhelming pain)**	**3.71**	**2.99**	**2.67**	**2.31**
Q2. Have any other symptoms (e.g. nausea, coughing or constipation) been affecting how you feel in the last 3 days?	**0 (not at all) - 5 (overwhelmingly)**	**2.57**	**2.02**	**1.55**	**1.47**
Q3. Have you been feeling worried about your illness in the past 3 days?	**0 (not at all) - 5 (overwhelming worry)**	**3.44**	**2.75**	**2.41**	**2.27**
Q4. Over the past 3 days, have you been able to share how you are feeling with your family or friends?	**0 (not at all) - 5 (yes, I've talked freely)**	3.41/ **1.59**	3.79/ **1.21**	3.94/ **1.06**	4.03/ **0.97**
Q5. Over the past 3 days have you felt that life was worthwhile?	**0 (no, not at all) - 5 (Yes, all the time)**	2.01/ **2.99**	2.49/ **2.51**	2.93/ **2.07**	2.85/ **1.90**
Q6. Over the past 3 days, have you felt at peace?	**0 (no, not at all) - 5 (Yes, all the time)**	1.84/ **3.16**	2.36/ **2.64**	2.70/ **2.30**	2.75/ **2.25**
Q7 Have you had enough help and advice for your family to plan for the future?	**0 (not at all) - 5 (as much as wanted)**	2.81/ **2.19**	3.64/ **1.36**	3.87/ **1.13**	3.99/ **1.01**
Q8. How much information have you and your family been given?	**0 (none) - 5 (as much as wanted) N/A**	3.28/ **1.72**	3.95/ **1.05**	4.31/ **0.69**	4.49/ **0.51**
Q9. How confident does the family feel caring for ____?	**0 (not at all) - 5 (very confident) N/A**	4.07/ **0.93**	4.32/ **0.68**	4.44/ **0.56**	4.41/ **0.59**
Q10. Has the family been feeling worried about the patient over the last 3 days?	**0 (not at all) - 5 (severe worry) N/A**	**3.14**	**2.58**	**2.21**	**2.16**
AVERAGE "GLOBAL SCORE" on a 0 – 5 scale where 0 is good		***2.54***	***1.98***	***1.67***	***1.54***

Table 4: Average Scores Male

		Visit 1	Visit 2	Visit 3	Visit 4
Q1. Please rate your pain (from 0 = no pain to 5 = worst/overwhelming pain) during the last 3 days	**0 (no pain) - 5 (worst/overwhelming pain)**	**4.02**	**3.21**	**2.81**	**2.31**

Q2. Have any other symptoms (e.g. nausea, coughing or constipation) been affecting how you feel in the last 3 days?	**0 (not at all) - 5 (overwhelmingly)**	**2.59**	**2.09**	**1.86**	**1.55**
Q3. Have you been feeling worried about your illness in the past 3 days?	**0 (not at all) - 5 (overwhelming worry)**	**3.31**	**2.54**	**2.14**	**1.81**
Q4. Over the past 3 days, have you been able to share how you are feeling with your family or friends?	**0 (not at all) - 5 (yes, I've talked freely)**	3.52/ **1.48**	3.91/ **1.09**	4.22/ **0.78**	4.33/ **0.67**
Q5. Over the past 3 days have you felt that life was worthwhile?	**0 (no, not at all) - 5 (Yes, all the time)**	1.86/ **3.14**	2.57/ **2.43**	2.97/ **2.03**	3.10/ **1.90**
Q6. Over the past 3 days, have you felt at peace?	**0 (no, not at all) - 5 (Yes, all the time)**	1.74/ **3.26**	2.45/ **2.55**	2.78/ **2.22**	2.98/ **2.02**
Q7 Have you had enough help and advice for your family to plan for the future?	**0 (not at all) - 5 (as much as wanted)**	3.12/ **1.88**	3.79/ **1.21**	4.17/ **0.83**	4.22/ **0.78**
Q8. How much information have you and your family been given?	**0 (none) - 5 (as much as wanted) N/A**	3.33/ **1.67**	4.11/ **0.89**	4.54/ **0.46**	4.67/ **0.33**
Q9. How confident does the family feel caring for ____?	**0 (not at all) - 5 (very confident) N/A**	4.11/ **0.89**	4.38/ **0.62**	4.48/ **0.52**	4.53/ **0.47**
Q10. Has the family been feeling worried about the patient over the last 3 days?	**0 (not at all) - 5 (severe worry) N/A**	**2.98**	**2.59**	**2.16**	**2.02**
AVERAGE "GLOBAL SCORE" on a 0 – 5 scale where 0 is good		***2.52***	***1.92***	***1.58***	***1.39***

Overall, each and every domain shows improvement over time. The "worst" problem overall is pain for both men and women. This is true for both the first and fourth visits. For the first visit the average pain score is 3.83, with the next worst score being that of anxiety (question 3) at 3.39. However by the fourth visit pain has a very close average score (2.31) to that of several other symptoms e.g. question 3 (anxiety, 2.10) and question 6 (sense of peace, 2.16).

Statistical analysis was done comparing the average pain level recorded at the first visit with that of the fourth visit (highlighted in Table 2). First the Shapiro-Wilk test was administered for checking for normal distribution in both first and fourth visits of each of the questions – not only for pain, but the other 9 questions as well. Table 5 (below) shows the results, indicating that the distributions are not "normal". Thus instead of the t-test, the Wilicoxon test for comparing the first visit vs. the fourth visit data sets was performed. Table 6 (next page) shows the results according to the correlating question of the APCA African POS. All domains showed a statistically significant change from first to fourth visit, with the p value in each instance being <0.0001. Thus from a clinical point of view, every domain of palliative care shows significant improvement over time. This includes improvement of moderate to severe cancer pain in the absence of a strong opioid.

Table 5: Shapiro-Wilk test for Visit 1 and Visit 4 for each Question								
Question	n	Mean	95% Confidence Interval	Variance	Standard Deviation	Coefficient of Variation	Shapiro-Wilk W	p
1. Pain first visit	145	3.8	3.7 to 4.0	1.0	1.0	26.3%	0.85	<0.0001
fourth visit	145	2.3	2.1 to 2.5	1.5	1.2	52.1%	0.92	<0.0001
2. Other Symptoms first	133	2.7	2.4 to 2.9	2.1	1.4	54.3%	0.92	<0.0001
fourth	133	1.5	1.3 to 1.7	1.7	1.3	87.7%	0.87	<0.0001
3. Anxiety first	133	3.4	3.1 to 3.6	2.4	1.5	45.4%	0.86	<0.0001
fourth	132	2.1	1.8 to 2.3	2.1	1.4	70.0%	0.92	<0.0001
4. Isolation first	133	3.5	3.2 to 3.8	2.7	1.6	46.9%	0.83	<0.0001
fourth	133	4.2	4.0 to 4.4	1.3	1.1	27.1%	0.74	<0.0001
5. Despair first	133	1.9	1.6 to 2.2	3.0	1.7	91.5%	0.87	<0.0001
fourth	133	3.0	2.7 to 3.2	2.7	1.7	56.0%	0.90	<0.0001
6. Peace first	133	1.8	1.6 to 2.1	2.4	1.5	83.6%	0.90	<0.0001
fourth	133	2.9	2.6 to 3.1	2.4	1.5	53.4%	0.92	<0.0001
7. Planning first	133	3.0	2.6 to 3.3	3.7	1.9	64.5%	0.84	<0.0001
fourth	133	4.1	3.9 to 4.3	1.3	1.2	28.4%	0.78	<0.0001
8. Information 1	133	3.3	3.0 to 3.6	2.8	1.7	50.4%	0.86	<0.0001
fourth	133	4.6	4.4 to 4.7	0.5	0.7	15.1%	0.66	<0.0001
9. Confidence in family caring 1	133	4.1	3.8 to 4.3	1.4	1.2	29.7%	0.77	<0.0001
fourth	133	4.4	4.3 to 4.6	0.8	0.9	20.5%	0.67	<0.0001
10. Family anxiety	133	3.1	2.8 to 3.3	2.5	1.6	51.5%	0.90	<0.0001
fourth	133	2.0	1.8 to 2.3	2.5	1.6	77.3%	0.91	<0.0001

Table 6: Wilcoxon test comparing Visit 1 to Visit 4 for each Question						
Question	n	Median difference	95% Confidence Interval	Wilcoxon's statistic	Z statistic	2-tailed p
1. Pain	145	1.5	1.5 to 1.5	5929	8.66	<0.0001
2. Other Symptoms	133	1.0	1.0 to 1.5	4487	7.42	<0.0001
3. Anxiety	132	1.5	1.0 to 1.5	4721	7.36	<0.0001
4. Isolation	133	-0.5	-0.5 to -0.5	350	-4.91	<0.0001
5. Despair	133	-1.0	-1.0 to -0.5	406.5	-6.63	<0.0001
6. Peace	133	-1.0	-1.5 to -0.5	853	-5.82	<0.0001
7. Planning	133	-1.0	-1.5 to -0.5	381.5	-5.90	<0.0001
8. Information	133	-1.0	-1.5 to -1.0	108.0	-7.26	<0.0001
9. Confidence in family caring	133	0.0	-0.5 to 0.0	88	-4.56	<0.0001
10. Family anxiety	133	1.0	0.5 to 1.5	3252	5.72	<0.0001

145 APCA African POS were completed filled in with regards to pain. For the remaining 9 questions all POS reports which had any blanks at all were not analysed. Thus for those 9 questions a total of 133 APCA African POS were assessed.

4.2 Nurse Interview Analysis

The 11 interviews were subjected to thematic analysis using a cut and paste approach. 6 interviews were with CHAT nurses (no access to oral morphine) and 5 interviews were with Selian nurses (consistent access to oral morphine). 4 major thematic areas were noted: morphine as a superior analgesic drug; holistic care as an important adjunct to pain management; and education of the family and patient as being very important, and palliative care being perceived as a life-prolonging service. Table 7 lists the sub-themes and themes.

Table 7: Themes and Sub-themes

Themes	Sub-themes
Morphine is Best	1. Belief that pain relief would be better with morphine 2. Morphine increases Nurse confidence in the ability to control pain 3. Cancer pain is almost always controlled with oral morphine
Holistic Care is important	1. Holistic care is very important especially when pain control is poor 2. Bereavement support is a usual and critical part of care 3. Palliative care is important even without morphine
Education is a valuable adjunct	
Palliative Care can extend life	

a) **Morphine is best for pain**

i) *Belief that Pain relief would be better with morphine*: 5 of 6 CHAT Nurses expressed the opinion that they could do a better job if they had oral morphine on hand for their patients.

"…if oral morphine was available people would find it less expensive and more effective than tramadol." (CHAT Nurse 4)

"The cases are few that are not helped by tramadol and ibuprofen, but these complicated cases with severe pain, I believe the availability of oral morphine would be a very big relief." (CHAT Nurse 6)

ii) *Morphine increases Nurse confidence in the ability to control pain*: 4 CHAT Nurses and 1 Selian Nurse commented on this point.

"It is a challenge (not having morphine), actually a very big one. You get there and you have nothing with which to help the pain. Sometimes the person needs help, and when you fail to deliver that help, it as if you have done nothing. They may even wonder why you bothered to visit." (CHAT Nurse 5)

"Having morphine gives us confidence that even if our patient is near the end of life, we can do something." (CHAT Nurse 1)

iii) *Cancer pain is almost always controlled with oral morphine*: the 5 Selian Nurses are unanimous on this point.

"I do not remember such a case of someone not being helped by oral morphine. Most patients get a good result." (Selian Nurse 3)

"I can't remember one when we had morphine and we could not control the pain." (Selian Nurse 5)

b) **Holistic Care provides important support beyond pain control.**

i) *Holistic care is very important especially with cases where pain control is poor*. 7 Nurses commented on this area, 2 from CHAT and 5 from Selian. There were no specific questions asking about holistic care; these comments came out in the case narratives. Comments ranged from paying attention to odour to consideration of psychosocial pain due to limb amputation.

"With our African setup you cannot simply say that now I managed the physical pain and everything is OK. There are other aspects of pain like the social pain, the spiritual pain and so on. They contribute a lot to pain and so if you are able to manage these

other pains like the social pain and the spiritual pain and psychosocial pain then you will find that to some extent a lot of these pains are associated with the physical. For example there might be family conflicts, or poverty, the child is not going to school, the breadwinner is unable to work; so you find some of these elements are adding pain into the physical pain." (CHAT Nurse 3)

"For such a case where pain is increasing even though we are giving the oral morphine, we have to do further assessment. It is possible that the pain is spiritual, or psychological, and not only physical. Such cases are here." (Selian Nurse 2)

ii) *Bereavement support is a usual part of the narration of care*. 3 CHAT Nurses and 1 Selian Nurse commented on follow-up care after the death of a client. Attendance at the funeral was the primary theme.

"Fortunately, we received the message of her death just after the event, and we had the chance to go as a team to attend the burial." (CHAT Nurse 2)

"...we had to embark on bereavement support and now we are supporting the family; the family wanted to share the properties and we worked so far to provide the death certificate. They are planning next month to start sitting down to plan." (CHAT Nurse 3)

iii) *Palliative Care is important even without morphine.* This was a specific question near the end of each interview: how did the Nurse feel about palliative care being delivered without oral morphine being available? The response was unanimous in affirming that palliative care had value even without oral morphine.

"By staying so close to patients and continuously asking them about pain, we keep hearing that their pain is getting better. And this is without morphine." (CHAT Nurse 2)

"Palliative care is not just oral morphine. It takes the holistic

approach, considering not only physical but also spiritual, psychological, and social aspects. Pain can still be addressed with locally available drugs. At least having tramadol, paracetamol, and ibuprofen should allow a team to work with most pain." (Selian Nurse 2)

c) **Education for patients and families is a valuable adjunct to care.** 5 Nurses (3 from CHAT, 2 from Selian) commented specifically on education as being an important part of their care.

"They had given up, but we also showed them how to do wound dressings, how to continue with medications, so that they cared for her up to the time of her death." (Selian Nurse 1)

"So we try to spend time to educate and comfort families because the result is that they get peace. Also, for them to understand that the particular illness does not have a cure; that their goals would be for the patient to be free of pain, and also that the family not get pain from the patient's pain. That is the big thing that we try to do, in comforting and educating families." (Selian Nurse 3)

d) **Palliative Care can extend life:** some comments did not fit into other categories and/or were too few to merit separate consideration as themes. A few quotes had to do with care and pain control as related to life expectancy.

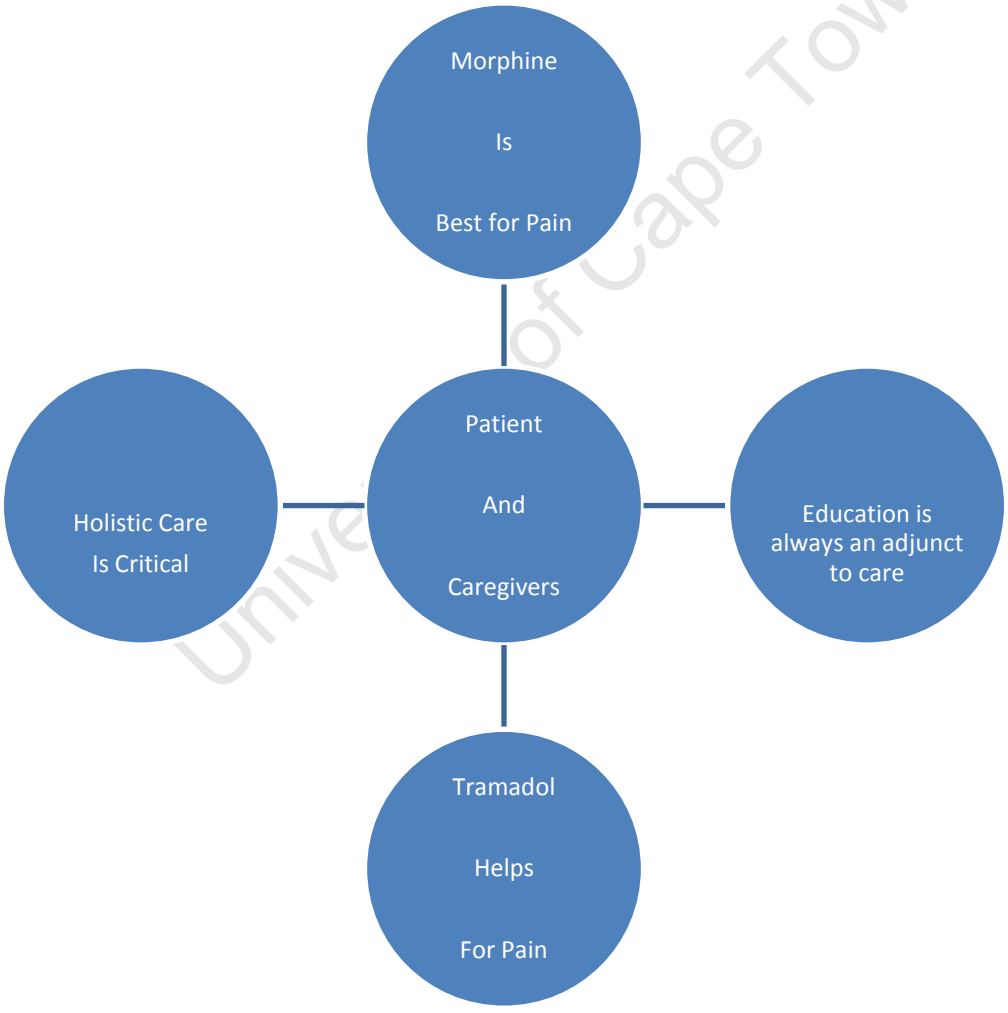
"Pain makes people feel devastated and that is the end of the world, and sometimes they give up and die." (CHAT Nurse 3)

"...it was not the pain that killed her; rather it was her disease, the cancer. Her pain was well-controlled up to the end." (Selian Nurse 1)

"…our patients with severe pain are so grateful to be under palliative care services, and to be visited. Many believe that without the care and treatment including attention to pain, they would have stopped eating and died some time ago." (CHAT Nurse 2)

Figure 1 is another way of visualizing the results of the data analysis plus nursing interview analysis. That tramadol has a significant effect is supported by the APCA African POS data. That morphine is better is emphasized by the palliative care nurses. Holistic care being effective has evidence from both the APCA African POS data plus the nurse interviews. Education is brought out as a specific additional point by the nurses.

Figure 1: Study Results in Diagram Format



5. Discussion

Is "quality" palliative care able to be delivered in the absence of oral morphine? This is one way of phrasing the research question of this study, and the results seem to indicate a very clear "yes". Overall pain scores improved from an average of 3.8/5 to 2.3/5. Other quality of life indicators – non-pain symptoms, psychological, spiritual, and family issues - also improved significantly over time. Nurses also affirmed the value of palliative care even in the absence of oral morphine. There is no ambiguity, then: in this rural Tanzanian setting, palliative care is valuable, and offers a significant degree of pain control, even in the absence of oral morphine.

From the nursing side, there is an additional very clear point. With oral morphine, there is the belief that pain control is even better. Nurses working with morphine were unanimous in expressing confidence in dealing with cancer: "I do not remember such a case of someone not being helped by oral morphine" (Selian Nurse 3). Likewise, nurses without morphine all recalled difficult cases which may have been better had they only been able to access that drug.

What are the weaknesses of this study? Some potential ones might be:

- There is no study group of sites which do have access to oral morphine. It would have been a stronger study if a direct comparison would have been possible.
- Having only one investigator doing APCA African POS assessments, interviews, and translations. More than one investigator might have diminished any inherent bias coming from a single investigator.
- Many languages were used, possibly impacting on the validity of the APCA African POS as well as the interviews. Each rural community involved in this study works with 2 to 3 primary languages. While Swahili is the dominant language in Tanzania, there are more than 120 distinct languages in the country, which is reflected in the 13 rural sites of this study. Some APCA African POS interviews were conducted in a language other than Swahili. With nurse interviews and translation, cross-checking with another translator was not done due to cost and confidentiality concerns.

However, the APCA African POS has been tested in a variety of African

environments, with a variety of dominant languages. It is unlikely that the variances of rural Tanzania are strikingly different from those of Uganda, Kenya, South Africa, and Zimbabwe. Tanzania might actually have an advantage in being more standardized with language, as Swahili is well-understood by anyone who has attended primary level education.

Regarding potential investigator bias, that might be an inherent issue with having a single person doing the vast majority of the work. Cross-checking with colleagues and literature is helpful; a future or follow-up study might involve more than one investigator.

Do these limitations impact on the study findings? I would suggest that they do not. Low dose use of morphine is confirmed from other sites (Tapsfield and Bates)[25]. Thus it is not surprising that tramadol is efficacious in a large number of cases. There is even literature to suggest that, with more aggressive use of tramadol, pain outcomes might be even better[29,31], as these papers suggest a morphine to tramadol equianalgesic ratio of closer to 1:5, rather than the more traditional 1:10 or even 1:20. There is also experience in this literature of using up to 600 mg/d of oral tramadol, with equal or better side-effect profiles as compared to oral morphine. There is the suggestion, then, that more aggressive use of tramadol than what was done in the CHAT setting – with a maximum dose of 400 mg/d – might result in even better pain score results.

Results are also in line with other data from palliative care providers in Africa and the African Palliative Care Association[39]. Loy's work, again, shows the positive impact of palliative care for HIV clients. Certainly it is expected that, apart from pain, other domains would likewise improve with holistic, intentional care. As the nurse interviews point out, whether in wound care with odour control, bereavement support, or psychosocial and spiritual support, clients have a great appreciation and sense of improvement when receiving palliative care.

> "With our African setup you cannot simply say that now I managed the physical pain and everything is OK. There are other aspects of pain like the social pain, the spiritual pain and so on. They contribute a lot to pain and so if you are able to manage these other pains like the social pain and the spiritual pain and psychosocial pain then you will find that to some extent a lot of these pains are associated with the physical. For example there might be family conflicts, or poverty, the

child is not going to school, the breadwinner is unable to work; so you find some of these elements are adding pain into the physical pain." (CHAT Nurse 3)

"Palliative care is not just oral morphine. It takes the holistic approach, considering not only physical but also spiritual, psychological, and social aspects. Pain can still be addressed with locally available drugs. At least having tramadol, PCM, and ibuprofen should allow a team to work with most pain." (Selian Nurse 2)

The APCA data, also not yet published, showed an average pain score of 1.79/5 for cancer patients (n=89) who do have access to oral morphine and have been assessed multiple times[45]. This compares to 2.31/5 in the current study. Thus there is evidence to suggest that pain control is indeed better with oral morphine, even though a direct comparison was not undertaken. APCA African POS data is not available from the Selian team, which otherwise would have been a good source for comparison. This would be an area for further study, utilizing data from the APCA African POS from rural Tanzanian sites which have access to oral morphine.

What if tramadol was dosed more aggressively? And what if the teaching regarding the WHO analgesic ladder was altered to suggest that tramadol is as potent as morphine in the Tanzanian setting? There is the likelihood, not yet evaluated, that pain control would be even better, and approaching that expected from the use of oral morphine.

In this study, nurse interviews affirm that oral morphine would be a preferable analgesic to tramadol, with only 1 of 13 nurses not being sure about wanting access to morphine for palliative care delivery.

"I am sure that things would be different if we had oral morphine. It is likely that pain would decrease more, and that with less pain the patient would have more faith." (CHAT Nurse 5)

"The cases are few that are not helped by tramadol and ibuprofen, but these complicated cases with severe pain, I believe the availability of oral morphine would be a very big relief." (CHAT Nurse 6)

The one exception, CHAT Nurse 2, says: "Since I started using these

> usual drugs so well, having morphine would be a real challenge for me. By staying so close to patients and continuously asking them about pain, we keep hearing that their pain is getting better. And this is without morphine."

Notably, Selian nurses were extremely confident in achieving pain control with oral morphine.

> "No, I do not recall such cases." (Cancer pain not controlled with morphine). (Selian Nurse 2)

> "I do not recall someone whose cancer pain does not respond to morphine. If the pain increases, we titrate the dose accordingly." (Selian Nurse 1)

> "I do not think so. I don't have any patient like that. I can't remember one when we had morphine and we could not control the pain." (Selian Nurse 5)

There seems little danger of palliative care teams becoming complacent in their pursuit of oral morphine access. It might be construed that this study is a rationale for governments *not* to allow opioid access. However, the strong international influence and training regarding opioid necessity for any quality of care is a definite push for the palliative care professionals delivering care to continuously advocate for oral morphine. Richard Smith, former editor of the British Medical Journal, commented on attending a meeting about global palliative care: "Some 80% of people in the world lack access to morphine, and, as Anne Merriman, a pioneer of palliative care in Africa, says "Palliative care without morphine is only supportive care." The point was made forcefully at the meeting that "Lack of access to morphine is torture"[46].

This last point, the pursuit of oral morphine, is an ongoing challenge for many palliative care advocates around the world. This study, and indeed the CHAT project and its associated emphasis on quality measurement, is an important advocacy for accessing oral morphine and for palliative care in general. The provision of client-centred data is valuable in care provision. Typical measures for quality of care tend to focus on care provision (e.g. co-trimoxazole or ARV adherence in HIV care, or access to radiation and/or chemotherapy in cancer care). The information can help to guide policy

making and health guidance from the government side. Indeed, as Mmbando describes, it is due to this very emphasis on quality and advocacy that 12 of 13 CHAT sites (including all sites from which the Nurse interviewees come) have, as of February 2011, been granted approval for oral morphine use by the Tanzania Food and Drug Authority[47].

Hearn and Higgenson, in their 1997 review of over 20 different quality of life tools for palliative care, suggest that there are four potential purposes in measuring quality of life[48]. Firstly, in order to provide clinical feedback for those who are gathering the data. In this respect, the experience with CHAT was positive. As teams learned and became comfortable with the tool, reliable and timely clinical feedback happened. Interventions were implemented and impacted outcomes. Secondly, the measures serve as an audit of services. Again, the experience in this setting was positive. Outcomes were found to be positive in every domain measured, providing important positive feedback to teams, hospital management, and funders. Third, the measure can be an indicator of the value of a service as compared to before its implementation. Here baseline "Visit 1" information is a fair indicator of usual care and outcomes without palliative care intervention. These are measures for people who have been through hospital systems and have a terminal diagnosis. Their baseline prior to intervention: 3.8/5 pain, 3.4/5 anxiety, to mention the highest, all show significant improvement over time. Finally, the information becomes a resource for health systems in determining the value of paying for a service. Governments and other funders of health care are able to look at this information and see improvement as measured by profoundly ill individuals and their families. Even without the best of tools, outcomes are very good. Will purchasers of health care, particularly in a resource-constrained environment, include palliative care? This research indicates that such a purchase might be expected to bring tangible results, even without oral morphine. With oral morphine, the results would be expected to improve even more.

6. Conclusion

Even without access to oral morphine, palliative care is a potent intervention for pain control and other quality of life measures. Tramadol provides a significant degree of pain relief even as a weak opioid, or "Level 2" analgesic according to the WHO analgesic ladder. Nurses, however, are very aware of tramadol's limitations in treating severe cancer pain, and are clear in having a preference for oral morphine.

In 2009 the theme for the World Hospice Day was "Discovering your voice" (http://www.worldday.org/news/discover-your-voice/). The cancer patients in this study were given a voice, telling us that palliative care is valuable with and without the provision of oral morphine. Palliative care nurses also have a voice, and clearly state that, while palliative care is important, access to oral morphine is also very important. As stated by Selian Nurse 5: "With palliative care, it's not only morphine. It is morphine plus other cares that we have to give. It is not a must that we have morphine, though it is critically needed, even in the rural areas. In all of the health facilities it is needed, but palliative care is not only morphine. We still have to give other cares, like spiritual care, the physical, the social and the psychological. So, if they do not have morphine, yes, they can give the other analgesics, but still palliative care can continue with the other cares that we are supposed to give. But while doing that we have to still look for some ways to get morphine, because there are so many patients in the rural areas who have cancer and they need morphine because of their pain. And pain is really very destructive to patients, so something needs to be done; it needs to be taken care of."

Finally, the history of the CHAT program and the ongoing advocacy done by teams and supervisors clearly shows that palliative care provision in itself is an advocacy tool for accessing that most critical of analgesic drugs for cancer pain: oral morphine.

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Table 2: Average Scores per Visit

		Visit 1	Visit 2	Visit 3	Visit 4
Q1. Please rate your pain (from 0 = no pain to 5 = worst/overwhelming pain) during the last 3 days	**0 (no pain) - 5 (worst/overwhelming pain)**	***3.83***	**3.08**	**2.72**	***2.31***
Q2. Have any other symptoms (e.g. nausea, coughing or constipation) been affecting how you feel in the last 3 days?	**0 (not at all) - 5 (overwhelmingly)**	**2.58**	**2.05**	**1.68**	**1.50**
Q3. Have you been feeling worried about your illness in the past 3 days?	**0 (not at all) - 5 (overwhelming worry)**	**3.39**	**2.67**	**2.31**	**2.10**
Q4. Over the past 3 days, have you been able to share how you are feeling with your family or friends?	**0 (not at all) - 5 (yes, I've talked freely)**	3.46/ **1.54**	3.84/ **1.16**	4.06/ **0.94**	4.15/ **0.85**
Q5. Over the past 3 days have you felt that life was worthwhile?	**0 (no, not at all) - 5 (Yes, all the time)**	1.95/ **3.05**	2.52/ **2.48**	2.94/ **2.06**	2.95/ **2.05**
Q6. Over the past 3 days, have you felt at peace?	**0 (no, not at all) - 5 (Yes, all the time)**	1.80/ **3.20**	2.39/ **2.61**	2.73/ **2.27**	2.84/ **2.16**
Q7 Have you had enough help and advice for your family to plan for the future?	**0 (not at all) - 5 (as much as wanted)**	2.94/ **2.06**	3.70/ **1.30**	3.99/ **1.01**	4.08/ **0.92**
Q8. How much information have you and your family been given?	**0 (none) - 5 (as much as wanted) N/A**	3.30/ **1.70**	4.01/ **0.99**	4.40/ **0.60**	4.63/ **0.37**
Q9. How confident does the family feel caring for ___?	**0 (not at all) - 5 (very confident) N/A**	4.09/ **0.91**	4.34/ **0.66**	4.45/ **0.55**	4.46/ **0.54**
Q10. Has the family been feeling worried about the patient over the last 3 days?	**0 (not at all) - 5 (severe worry) N/A**	**3.08**	**2.58**	**2.19**	**2.10**
AVERAGE "GLOBAL SCORE" on a 0 – 5 scale where 0 is good		***2.53***	***1.96***	***1.63***	***1.49***

Table 3: Average Scores Female

		Visit 1	Visit 2	Visit 3	Visit 4
Q1. Please rate your pain (from 0 = no pain to 5 = worst/overwhelming pain) during the last 3 days	**0 (no pain) - 5 (worst/overwhelming pain)**	**3.71**	**2.99**	**2.67**	**2.31**
Q2. Have any other symptoms (e.g. nausea, coughing or constipation) been affecting how you feel in the last 3 days?	**0 (not at all) - 5 (overwhelmingly)**	**2.57**	**2.02**	**1.55**	**1.47**
Q3. Have you been feeling worried about your illness in the past 3 days?	**0 (not at all) - 5 (overwhelming worry)**	**3.44**	**2.75**	**2.41**	**2.27**
Q4. Over the past 3 days, have you been able to share how you are feeling with your family or friends?	**0 (not at all) - 5 (yes, I've talked freely)**	3.41/ **1.59**	3.79/ **1.21**	3.94/ **1.06**	4.03/ **0.97**
Q5. Over the past 3 days have you felt that life was worthwhile?	**0 (no, not at all) - 5 (Yes, all the time)**	2.01/ **2.99**	2.49/ **2.51**	2.93/ **2.07**	2.85/ **1.90**
Q6. Over the past 3 days, have you felt at peace?	**0 (no, not at all) - 5 (Yes, all the time)**	1.84/ **3.16**	2.36/ **2.64**	2.70/ **2.30**	2.75/ **2.25**
Q7 Have you had enough help and advice for your family to plan for the future?	**0 (not at all) - 5 (as much as wanted)**	2.81/ **2.19**	3.64/ **1.36**	3.87/ **1.13**	3.99/ **1.01**
Q8. How much information have you and your family been given?	**0 (none) - 5 (as much as wanted) N/A**	3.28/ **1.72**	3.95/ **1.05**	4.31/ **0.69**	4.49/ **0.51**
Q9. How confident does the family feel caring for ____?	**0 (not at all) - 5 (very confident) N/A**	4.07/ **0.93**	4.32/ **0.68**	4.44/ **0.56**	4.41/ **0.59**
Q10. Has the family been feeling worried about the patient over the last 3 days?	**0 (not at all) - 5 (severe worry) N/A**	**3.14**	**2.58**	**2.21**	**2.16**
AVERAGE "GLOBAL SCORE" on a 0 – 5 scale where 0 is good		***2.54***	***1.98***	***1.67***	***1.54***

Table 4: Average Scores Male

		Visit 1	Visit 2	Visit 3	Visit 4
Q1. Please rate your pain (from 0 = no pain to 5 = worst/overwhelming pain) during the last 3 days	**0 (no pain) - 5 (worst/overwhelming pain)**	**4.02**	**3.21**	**2.81**	**2.31**
Q2. Have any other symptoms (e.g. nausea, coughing or constipation) been affecting how you feel in the last 3 days?	**0 (not at all) - 5 (overwhelmingly)**	**2.59**	**2.09**	**1.86**	**1.55**
Q3. Have you been feeling worried about your illness in the past 3 days?	**0 (not at all) - 5 (overwhelming worry)**	**3.31**	**2.54**	**2.14**	**1.81**
Q4. Over the past 3 days, have you been able to share how you are feeling with your family or friends?	**0 (not at all) - 5 (yes, I've talked freely)**	3.52/ **1.48**	3.91/ **1.09**	4.22/ **0.78**	4.33/ **0.67**
Q5. Over the past 3 days have you felt that life was worthwhile?	**0 (no, not at all) - 5 (Yes, all the time)**	1.86/ **3.14**	2.57/ **2.43**	2.97/ **2.03**	3.10/ **1.90**
Q6. Over the past 3 days, have you felt at peace?	**0 (no, not at all) - 5 (Yes, all the time)**	1.74/ **3.26**	2.45/ **2.55**	2.78/ **2.22**	2.98/ **2.02**
Q7 Have you had enough help and advice for your family to plan for the future?	**0 (not at all) - 5 (as much as wanted)**	3.12/ **1.88**	3.79/ **1.21**	4.17/ **0.83**	4.22/ **0.78**
Q8. How much information have you and your family been given?	**0 (none) - 5 (as much as wanted) N/A**	3.33/ **1.67**	4.11/ **0.89**	4.54/ **0.46**	4.67/ **0.33**
Q9. How confident does the family feel caring for ____?	**0 (not at all) - 5 (very confident) N/A**	4.11/ **0.89**	4.38/ **0.62**	4.48/ **0.52**	4.53/ **0.47**
Q10. Has the family been feeling worried about the patient over the last 3 days?	**0 (not at all) - 5 (severe worry) N/A**	**2.98**	**2.59**	**2.16**	**2.02**
AVERAGE "GLOBAL SCORE" on a 0 – 5 scale where 0 is good		***2.52***	***1.92***	***1.58***	***1.39***

Each red cross represents an ELCT hospital. 4 additional hospitals have opened or are in the process of opening, 3 located in the northeast and 1 located in the far northwest.

APCA AFRICAN PALLIATIVE OUTCOME SCALE

Patient Number _____	Possible Responses	Visit 1	Visit 2	Visit 3	Visit 4
ASK THE PATIENT					
Q1. Please rate your pain (from 0 = no pain to 5 = worst/overwhelming pain) during the last 3 days	0 (no pain) - 5 (worst/overwhelming pain)				
Q2. Have any other symptoms (e.g. nausea, coughing or constipation) been affecting how you feel in the last 3 days?	0 (not at all) - 5 (overwhelmingly)				
Q3. Have you been feeling worried about your illness in the past 3 days?	0 (not at all) - 5 (overwhelming worry				
Q4. Over the past 3 days, have you been able to share how you are feeling with your family or friends?	0 (not at all) - 5 (yes, I've talked freely				
Q5. Over the past 3 days have you felt that life was worthwhile?	0 (no, not at all) - 5 (Yes, all the time)				
Q6. Over the past 3 days, have you felt at peace?	0 (no, not at all) - 5 (Yes, all the time)				
Q7 Have you had enough help and advice for your family to plan for the future?	0 (not at all) - 5 (as much as wanted)				
ASK THE FAMILY CARER					
Q8. How much information have you and your family been given?	0 (none) - 5 (as much as wanted) N/A				
Q9. How confident does the family feel caring for ____?	0 (not at all) - 5 (very confident) N/A				
Q10. Has the family been feeling worried about the patient over the last 3 days?	0 (not at all) - 5 (severe worry) N/A				

Study Title: <u>Assessing the Quality of Palliative Care in Rural Tanzania where Availability of Oral Morphine is Intermittent or Absent</u>

Kristopher Hartwig MD
0784 829328
hartwig@elct.or.tz

I am undertaking a Masters Degree in Palliative Care out of the University of Capetown in South Africa. Part of the research of the above study is to conduct interviews with Nurses who are involved with the delivery of palliative care.

The interview is designed to be about 30 minutes in length. You will be asked some basic questions about the challenges of helping people with severe pain, especially those living with cancer. If there are questions you prefer not to answer, you may feel free to move on. Should you desire to stop the interview at any point you may feel free to do so. You may also feel free to expand on the questions and talk about related issues according to your experience.

All of the information will be kept confidential with regards to names of those being interviewed. The data will be kept in a secure place during and after the study. The results will be submitted to the University of Capetown.

Participant's Agreement:
I understand that my participation in the interview is entirely voluntary. I understand the intent and purpose of the research. If I wish to stop the interview for any reason, I may do so without having to give an explanation.

The researcher has reviewed the particular benefits and risks of this project with me. I understand that this study is part of a course being undertaken by the researcher. I understand that the results will be available through the library of the U. of Capetown. I have the right to withdraw or review any information I have given prior to the submission of the results. I understand that the data is to be collected by way of tape recording, and will be kept confidential in regards to my personal identity. If I choose to have the tape stopped and erased to any extent, I am free to do so.

Should I have any questions about this study I may contact the researcher. I have been offered a copy of this consent form for my own reference.

I have read the above form and consent to the interview which is to be conducted today.

Participant's Name:_____

Participant's Signature:_____

Interviewer's Signature:_____

Date:_____

Date:

To: Doctor In Charge/Director

Lutheran Hospital:

Re: **Notice of Research Being Conducted in Palliative Care**

Please regard the above heading. I am presently enrolled in the Masters Degree in Palliative Care out of the University of Capetown in South Africa. My research thesis is entitled: "Assessing the Quality of Palliative Care in Rural Tanzania where Availability of Oral Morphine is Intermittent or Absent."

There are two components to this research. One is a retrospective analysis of data which has already been collected through our CHAT program, in particular the APCA POS which your team uses as an assessment tool on a regular basis. This data will be assessing pain control and quality of life for people living with cancer who have been served by your palliative care team. Our database does not have the patient names, but rather only their identification numbers, thereby assuring complete confidentiality.

The second component of the research is to conduct interviews with Nurses who are directly involved in Palliative Care. It is possible that we will be asking your Palliative Care Nurse to participate in one the interviews. In that event the interview would happen during a site visit from our CHAT team or during one of the management meetings in Arusha. The names of interviewees will be kept confidential.

This research will have passed through all relevant channels of the Tanzania National Medical Research Institute prior to the initiation of any activities.

Your consent for this process will be most appreciated. For any questions or concerns please contact me directly.

Sincerely,

Kristopher Hartwig MD

Palliative Care Coordinator
ELCT

UNIVERSITY OF CAPE TOWN

Health Sciences Faculty
Faculty of Health Sciences Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
e-mail: sumayah.ariefdien@uct.ac.za

05 August 2010

HREC REF: 319/2010

Dr K Hartwig
c/o Dr Elma De Vries
School of Public Health & Family Medicine

Dear Dr Hartwig

PROJECT TITLE: AN EVALUATION OF PALLIATIVE CARE IN RURAL TANZANIA WHERE AVAILABILITY OF ORAL MORPHINE IS INTERMITTENT OR ABSENT

Thank you for submitting your study to the Health Science Faculty Research Ethics Committee for review

It is a pleasure to inform you that the Ethics Committee has **formally approved** the above-mentioned study.

Approval is granted for one year till the 15th August 2011.

Please submit a progress form, using the standardised Annual Report Form (FHS016), if the study continues beyond the approval period. Please submit a Standard Closure form (FHS010)if the study is completed within the approval period.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
sAriefdien

This serves to confirm that the University of Cape Town Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

The Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

THE UNITED REPUBLIC OF
TANZANIA

National Institute for Medical Research
P.O. Box 9653
Dar es Salaam
Tel: 255 22 2121400/390
Fax: 255 22 2121380/2121360
E-mail: headquarters@nimr.or.tz
NIMR/HQ/R.8a/Vol. IX/1025

Ministry of Health and Social Welfare
P.O. Box 9083
Dar es Salaam
Tel: 255 22 2120262-7
Fax: 255 22 2110986

21st October 2010

Dr Kristopher Hartwig
Evangelical Lutheran Church of Tanzania
P O Box 3033, ARUSHA
C/O Dr Paul Z Mmbando
Evangelical Lutheran Church of Tanzania
P O Box 3033, ARUSHA

CLEARANCE CERTIFICATE FOR CONDUCTING MEDICAL RESEARCH IN TANZANIA

This is to certify that the research entitled: An Evaluation of Palliative Care in Rural Tanzania where Availability of Oral Morphine is Intermittent or Absent, (Hartwig K et *al)*, whose Local Investigator is Dr Paul Mmbando, Manager, ELCT Palliative Care Project, Arusha , Tanzania , has been granted ethics clearance to be conducted in Tanzania.
The Principal Investigator of the study must ensure that the following conditions are fulfilled:

1. Annual Progress report is submitted to the Ministry of Health and the National Institute for Medical Research, Regional and District Medical Officers.
2. Permission to publish the results is obtained from National Institute for Medical Research.
3. Copies of final publications are made available to the Ministry of Health & Social Welfare and the National Institute for Medical Research.
4. Any researcher, who contravenes or fails to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine. NIMR Act No. 23 of 1979, PART III Section 10(2).
5. Approval is for one year: 21st October 2010 to 20th October 2011.

Name: Dr Mwelecele N Malecela

Signature
ACTING CHAIRPERSON
MEDICAL RESEARCH
COORDINATING COMMITTEE

Name: Dr Deo M Mtasiwa

Signature
CHIEF MEDICAL OFFICER
MINISTRY OF HEALTH, SOCIAL WELFARE

CC: RMO
DMO

Interview Guide

1. Introduction of the Nurse including site of work and personal history in palliative care work.
2. Have the Nurse describe in detail the case of a patient with cancer who, while under their team's care, had poor pain control.
3. Have the Nurse describe in detail the case of a patient with cancer who, while under their team's care, had very good pain control.
4. Ask the Nurse to reflect on the value of palliative care in the setting of no access to oral morphine for chronic pain control.